

Remarks

Claims 1-17 and 20-39 are pending. Claims 4, 8-11, and 29-30 stand withdrawn.

Amendments to the Claims

Claim 1 has been amended to more clearly define the implantable drug delivery module. It now is expressly recited that each discrete reservoir cap is *in register with an opening* of one of the plurality of reservoirs which are defined in the substrate. Support can be found, for example, in Figures 6B and 6C, which shows discrete reservoir caps 66 in register with reservoirs 62 in substrate/body 64. *See also* incorporated-by-reference U.S. Patent Application Publication No. 2004/0121486, at for example Figures 1-4 and 6-8.

Claim 23 has been amended into independent form and to explicitly indicate that an electric current is passed through the discrete reservoir cap to disintegrate it by electrothermal ablation. Support for the amendment is found at least at page 14, lines 24-29.

New claims 37-39 have been added. Support for claims 37-38 can be found at least at page 10, lines 2-3, and page 14, lines 12-29. Support for new claim 39 is found at least in original claims 1 and 23.

Rejection under 35 U.S.C. § 103

Claims 1-3, 5, 7, 17, 20, 21, and 23-26 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 7,097,775 to Greenberg et al. (hereinafter "Greenberg") in view of U.S. Patent No. 6,349,232 to Gordon (hereinafter "Gordon"). Claims 6, 12-16, 22, 27, 28, 31, 32, 35, and 36 are rejected as obvious over Greenberg in view of Gordon and in further view of U.S. Patent Application Publication No. 2002/0111601 to Thompson (hereinafter "Thompson"). Claim 33 is rejected as obvious over Greenberg in view of Gordon, Thompson, and U.S. Patent

Application Publication No. 2002/0055761 to Mann et al. (hereinafter “Mann”). Claim 34 is rejected as obvious over Greenberg in view of Gordon, Thompson, and U.S. Patent No. 6,587,719 to Barrett et al. (hereinafter “Barrett”). The rejections are respectfully traversed.

Neither Greenberg nor Gordon Teaches a Neural Stimulation Electrode.

The Examiner appears to misunderstand Greenberg. At Col. 10, Lns. 12-19, Greenberg teaches neural stimulation by delivering *a drug*, not an electrical current, to provide focal stimulation of neural tissue.

The electrode 330 cited by the Examiner is used only for *iontophoresis*, not for engagement with or stimulation of neural tissue. Greenberg discloses an iontophoresis device having reservoirs containing neurotransmitter drugs. Each reservoir has an associated electrode charged by an electrical signal generator to cause the drug to be ejected in small amounts from the reservoir. Greenberg teaches neither a *stimulation electrode* nor an electrode for *operable for engagement with a neural tissue* of a patient.

Nothing in Gordon teaches neural stimulation or an electrode for engagement with neural tissue. In fact, nothing in Gordon teaches an electrode suitable for use with or on any biological tissue. Yet, at page 4 of the Office Action, the Examiner alleges that “Gordon discloses a stimulation electrode extends a distance from a hermetically sealed encasement (e.g., FIG. 11D, element 271)...” That is neither a fair nor accurate reading of Gordon, for at least the following three reasons.

First, Gordon teaches that electrodes 271 are “used to energize” cell enclosures 270. Electrode 217 is not mentioned to be suitable for stimulation of neural tissue. If the Examiner is

suggesting that any electrode inherently is suitable for neural tissue stimulation, then Applicants respectfully disagree. Every electrode is not *necessarily* suitable to function as a stimulation electrode, and inherency cannot be established by mere probabilities or possibilities.

Second, the Examiner intimates that cell enclosure 270 is identical or equivalent to the “hermetically sealed encasement” recited in Applicants’ claim 5. This is incorrect. It is not a reasonable interpretation of Gordon, because Gordon’s cell enclosure cannot simultaneously serve as a substrate defining the reservoirs and as the “hermetically sealed encasement containing the drug delivery module and microcontroller,” as required by claim 5.

Lastly, nothing in Gordon teaches that cell enclosure 270 is *hermetic*. Gordon fails to suggest anything about the cell enclosure in FIG. 11D needing or being capable of hermeticity, and the reference teaches nothing about using hermetic sealing materials.

For any one or all of the foregoing reasons, no *prima facie* case of obviousness has been established. The rejections must be withdrawn.

Gordon, Alone or in Combination with Other Cited Art,
Does Not Teach Electrothermal Ablation of a Discrete Reservoir Cap.

Applicants’ claimed device requires a means for disintegrating a discrete reservoir cap that is in register with a defined opening of a reservoir in the device. The disintegration must occur by *electrothermal ablation*. This term, as used by Applicants, is explained at page 14, lines 25-29:

When an effective amount of an **electrical current is applied through the leads and reservoir cap**, the temperature of the reservoir cap is locally increased due to resistive heating, and **the heat generated within the reservoir cap** increases the

temperature sufficiently to **cause the reservoir cap to be electrothermally ablated** (i.e., ruptured).

Applicants' discrete reservoir cap separates the reservoir contents from an environment outside of the reservoir, until the discrete reservoir cap is electrothermally ablated to uncover an opening in the reservoir. Thus, Applicants' reservoir cap serves as *both* a barrier covering a reservoir opening and, at least briefly during operation, a resistive heater. Gordon does not teach such an electrothermal ablation structure.

Gordon has a resistance heating element 272 placed against the outer surface of or imbedded in a cell enclosure 270, as illustrated in FIGS. 9, 10, and 11A-C. See Col. 3, Line 58 to Col. 4, Line 2. The electrical resistance heating element is a *distinct* structure from the cell enclosure. This is not a structure for "electrothermal ablation" according to Applicants' use of the quoted term.

Gordon teaches that *heat* must flow *from* heating element 272 *to* the cell enclosure 270. Even if the cell enclosure 270 melts, it is not electrothermal ablation, because the cell enclosure is not heating due to internally generated heat and because the resistance heating element is not a discrete cap covering a reservoir opening. Furthermore, Gordon teaches that heat from electrical resistance heating element 272 "causes the wall of cell enclosure 270 to break, melt, disintegrate or otherwise become permeable" (Col. 8, Lines 57-61) whereas with Applicants' claimed devices and methods, the internally generated heating of the reservoir cap causes the reservoir cap itself to disintegrate.

None of the embodiments in Gordon would be construed by one of ordinary skill in the art to teach or suggest electrothermal ablation. First, FIGS. 9-11D of Gordon do not show or disclose or suggest a *discrete* reservoir cap. Cell enclosure 270 is not a reservoir cap. It cannot reasonably be construed to be *both* a substrate *and* discrete reservoir cap in register with, or covering, a predefined opening of a reservoir. Gordon implies that the “cell enclosure” 270 means the entire body structure surrounding the pet care substance. Gordon’s description of the cell enclosure simply does not distinguish between a substrate structure and reservoir cap structure. A person of ordinary skill in the art therefore could not read FIGS. 9-11D as teaching any particular portion of cell enclosure 270 to correspond to a reservoir cap.

Gordon’s FIGS. 12A-B and FIGS. 21A-B and their description also fail to teach a reservoir opening means designed to open a reservoir by electrothermal ablation. In these figures, Gordon teaches that 289 is a “rupturable **opening**”. Because an “opening” is the *absence* of material and not a positive structure, one of ordinary skill in the art would understand rupturable opening 289 as illustrated in Fig. 12A and described at Col. 9, Ln. 50 to Col. 10, Ln. 23 to be a region of coversheet 290 that is intended to rupture. Rupturable opening 289 and coversheet 290 are not separate structures or materials.

Gordon does not teach connecting both an electrical input lead and an electrical output lead to rupturable opening 289. The rupturable opening region of the coversheet 289 is disclosed to be “in electrical communication with a heating element, as described hereinabove with reference to FIGS. 9-11D.” However, FIGS. 9-11D do not show a discrete reservoir cap, let alone teach rupture of a discrete reservoir cap by passing an electrical current precisely through a discrete reservoir cap closing off a predefined opening.

In addition, rupturable openings 289 cannot simultaneously meet the “reservoir cap” element of Applicants’ claims *and* still need a *separate* “heating element” in communication with it to cause the rupturable opening to open. With Applicants’ claimed devices in which the reservoir cap disintegrates by electrothermal ablation, the discrete reservoir cap *is* the heating element; Applicants’ device need not include a separate one. Gordon does not teach that structure 289 could or should serve *both* as a resistive heating element *and* structural boundary between the reservoir contents and outer environment.

Moreover, Gordon is silent as to appropriate materials of construction, dimensions of leads and cap materials, or any other design parameters necessary to achieve electrothermal ablation. For instance, there is no recognition that the reservoir cap and the input and output leads should be designed to provide upon the application of electrical current an increase in electrical current density in a reservoir cap relative to the current density in input and output leads.

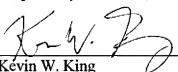
Nothing in Thompson, Mann, or Barrett, can be construed to supplement the deficiencies of Greenberg and Gordon. None of these references in any combination remotely suggest means or structures for disintegrating a reservoir cap by electrothermal ablation.

For the foregoing reasons, no *prima facie* case of obviousness has been established. The rejections must be withdrawn.

Conclusions

The claims as amended are patentable over the prior art of record. Prompt allowance of each of the pending claims is therefore respectfully solicited.

Respectfully submitted,



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